

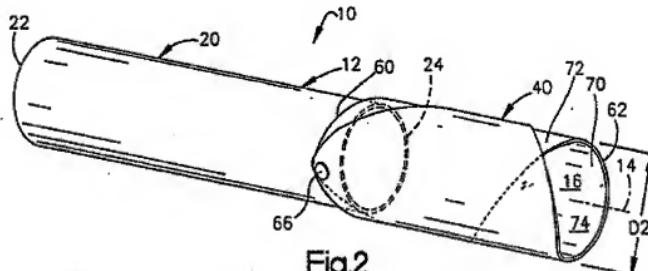
REMARKS

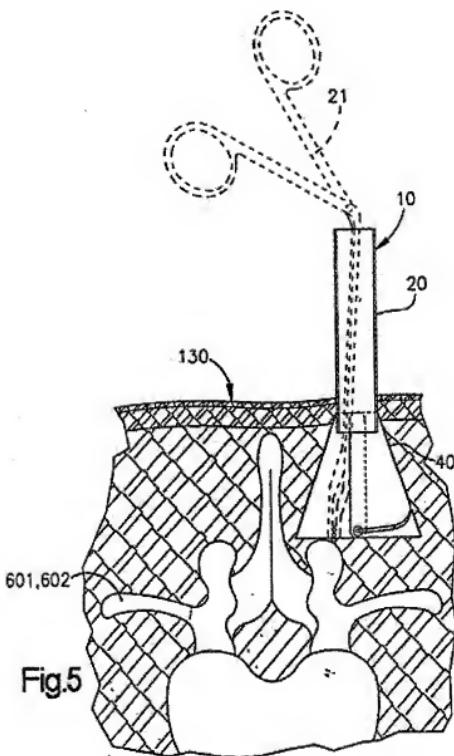
Prior to this amendment, Claims 18-41 were pending in this application. Claims 18 and 33 have been amended to correct inadvertent typographical errors, and Claims 42-48 have been added. Accordingly, Claims 18-48 remain pending.

Discussion of a Preferred Embodiment

Broadly, this application is directed to systems of treating a patient's spine. More particularly, in one embodiment, this application discloses a system of accessing the spine and coupling implants therewith.

Figures 2 and 5 (reproduced below) illustrate a portion of such a system including an access device adapted for insertion into the body of the patient. One example of an access device is a cannula 10 illustrated in Figures 2 and 5.





The access devices usable in the systems disclosed in certain embodiments of this application can include an elongate body that has a proximal and distal end, an outer surface, and an inner surface. The inner surface can define an access path that extends through the elongate body through which surgical instruments, implants and fasteners can be inserted to a surgical location proximate the spine.

The access device of Figures 2 and 5 is an example of an access device that can be expanded or otherwise configured so that the cross-sectional area (or a transverse dimension) of the access path at a first location is greater than the cross-sectional area (or transverse dimension)

of the access path at a second location, wherein the first location is distal to the second location. As shown in Figure 2, the access device can have a first or reduced configuration adapted for insertion through an incision on the patient's skin. Once the access device has been advanced to the desired spinal location, the access device can be expanded, for example, as shown in Figure 5.

After access to the spinal location has been provided through the access device, a vertebral fixation assembly, such as the vertebral fixation assembly 620 in Figures 24 and 25 (reproduced below), or fasteners, such as the fasteners 640, can be moved through the access device to the surgical location and coupled with a vertebra. For example, the vertebral fixation assembly 620 can be coupled to adjacent vertebrae 601, 602, as shown in Figure 24 and 27.

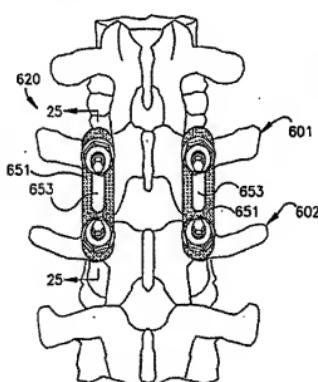


Fig.24

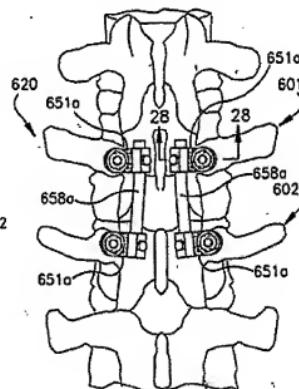


Fig.27

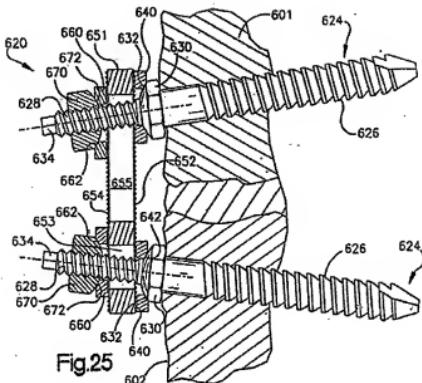


Fig.25

Obviousness Rejection

Claims 18-41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over various combinations of Foley et al. (U.S. Patent No. 5,792,044), Ash (WO 83/03189), Matthews (U.S. Patent No. 6,033,406), Justis (U.S. Patent No. 6,293,949), and Heinig (US Patent No. 4,887,595).

Foley et al.

The Examiner asserts that Column 15, lines 3-20, of Foley teaches a system comprising an elongated body that can be useable with at least two fasteners. See Office Action, page 2, ¶ 2. Applicant respectfully disagrees with the Examiner's assertion and respectfully submits that Foley fails to teach or suggest the specific combination of features recited by each of Applicant's claims. Moreover, as discussed further below, Foley is not combinable with the other references, and could not properly be modified, as cited by the examiner in the rejections of the claims.

Foley is directed to a device 10 (Figure 1, reproduced below) for percutaneous surgery that includes an elongated cannula 20 having a first inner diameter D_1 and an outer diameter D_0 sized for percutaneous introduction into a patient. The cannula 20 also includes a distal working end 21 and an opposite proximal end 22. The cannula 20 defines a working channel 25 between the ends 21, 22 having a second diameter d_2 equal to the first inner diameter D_1 and sized for receiving a tool therethrough.

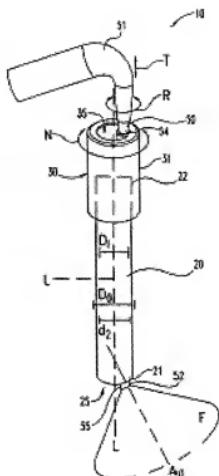


Fig. 1

The cannula 20 is configured to be inserted over a dilator. This step is illustrated in Figure 10e. See Foley, Col. 10 at lines 35-59.

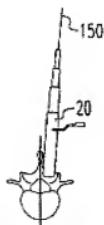


Fig. 10e

The cannula is described as having a "maximum diameter d_2 " of 12.7 mm, with the effective working space being only about 8 mm due to the presence of a viewing element 50. See Foley, Col. 12 at lines 29-35. Although Foley says that his invention "is not limited to particular sizes for the working channel" (Column 12, line 36), there is no suggestion to make the Foley

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cannula large enough to make the diameter d_2 large enough to permit passage of multiple fasteners therethrough to perform procedures discussed in certain embodiments of the present application, which are disclosed as being performed by accessing two adjacent vertebrae through a single device that is capable of simultaneously exposing both vertebrae.

Most of the procedures disclosed by Foley are performed at a single site (a single disc space or a portion of one vertebra, such as a single pedicle or lamina of a vertebra). See e.g., Column 13, lines 48-54; column 15, lines 44-48; Figures 10e-10i. Though Foley states at column 4, lines 12-15 that "all steps of a surgical procedure are conducted under direct vision through a single working channel cannula," where a procedure is performed over a larger area (e.g., a procedure involving access to pedicles on adjacent vertebra), Foley teaches removing the cannula 20 and then re-inserting it at another location either up or down the spine. For example, Foley teaches that such procedures are conducted by "sequentially inserting the working channel cannula 20 through *several small cutaneous incisions along the spinal midline*" or by placing several working channel cannulae 20 "at *each of the small cutaneous incisions*." Foley, Col. 13, line 60 – Col. 14, line 2 (emphasis added).

Thus, Foley teaches a relatively small cannula that has to be repositioned using several small cutaneous incisions when the procedures involve an area that is significantly larger than the size of the cannula's cross-section at its distal end. Though Foley states in column 12, lines 3-15 that "the cannula can be readily positioned over an appropriate target tissue or bone, to thereby move the working space as necessary for the surgical procedure," there is no suggestion in Foley that such movement of the working space contemplates, for example, exposing adjacent vertebrae. Rather, Foley merely teaches that during a laminotomy such manipulation of the cannula can allow a greater region of bone removal on a single vertebra than defined by the inner diameter of the working channel of the cannula. See column 13, lines 54-62. Foley only suggests limited local manipulation of the cannula to access a space that is not significantly larger than that provided by the inner diameter of the working channel. For procedures involving a larger area, e.g., spanning multiple pedicles on adjacent vertebrae, Foley discusses performing such procedures by sequentially inserting the cannula, or inserting multiple cannulae, through multiple small cutaneous incisions, as discussed above.

Foley also teaches away from significantly enlarging the cannula 20. For example, Foley's cannula 20 is made small enough so that the K-wires, which had been used to position

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screws, are not needed to guide screws into position. Foley states that "the working channel itself can effectively operate as a positioning guide, once the cannula 20 is properly oriented with respect to the vertebra." Col. 15, lines 24-26. Foley also teaches that "the location of the bone screw within the vertebra is *critical*, so identification of the position of the cannula 20 over the bony site is necessary." Col. 15, lines 15-18. Increasing the size of the working channel to permit passage of *multiple* fasteners would reduce the accuracy of placement considered so critical by Foley. Accurate placement is also fostered, according to Foley, by "centering" his device over "an appropriate target tissue or bone." Col. 12, lines 3-9. Unless a much larger area contemplated by Foley were exposed by his cannula, neither pedicle in a fixation procedure could be considered to be at the center of the projection of Foley's working channel. Also, Foley teaches away from enlarging the cannula 20 to permit passage of multiple fasteners therethrough by teaching that special tools should be used with the cannula. More particularly, rather than increasing the size of the cannula 20 to accommodate more conventional tools, Foley teaches using very special tools that will not obstruct the surgeon's view, e.g., tools with 90° handles, as shown in Figures 4-8 and discussed at Column 12, lines 47-50.

Moreover, although Foley refers to fixation as a procedure that can be performed through the cannula 20, apparently by making several incisions on each side of the spine, Foley contains no teaching for a system for simultaneous delivery of multiple components of a fixation assembly or member through one cannula to fix, or span between fasteners or implants secured to, two adjacent vertebrae, let alone how to do so with the sizes and configurations of the cannula 20 disclosed. For example, though column 15, lines 3-11 in Foley state that "[t]he insertion of vertebral fixation elements can be accomplished through the device 10," Foley does not disclose providing simultaneous access to vertebral locations on two adjacent pedicles or other sites on vertebrae where fasteners can be inserted. Accordingly, the cannula in Foley is not configured to permit passage of at least two fasteners therethrough to fix two adjacent vertebrae. In contrast, an access device or elongate body configured for the insertion of such a fixation assembly and/or fasteners therethrough to fix two adjacent vertebrae is a feature recited in Applicant's claimed embodiments.

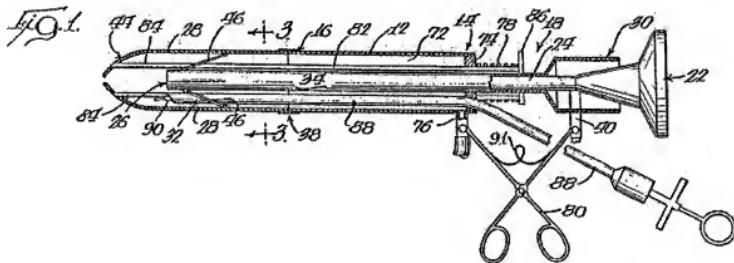
Applicant therefore submits that the cannula of Foley would not be suitable for the system recited in at least Claims 18-41, as Foley provides no teaching or suggestion that the fasteners or

vertebral fixation assembly, as recited in those claims, can be simultaneously inserted through the cannula of Foley to fix said fasteners or vertebral fixation assembly to two adjacent vertebrae.

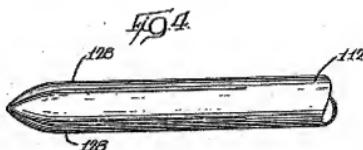
Ash

The Examiner asserts that Ash discloses "a device for use in minimally invasive surgical procedures and that comprises an elongated body that is expandable at the distal end in order to provide viewing and operation room." Office Action, page 2, ¶2. The Examiner asserts that it would have been obvious for one of ordinary skill in the art at the time of the invention to "manufacture the elongated body of Foley with the expandable distal end in view of Ash in order to provide viewing and operation room." Id. Applicant respectfully disagrees with the Examiner and respectfully submits that there is no motivation to combine Foley with Ash to provide the claimed invention in the present application, as discussed below.

Ash discloses an elongated external tube 12 having proximal end 14 and distal end 16 portions, with tissue retraction members 28 operably associated with the distal end portion 16. See Ash, page 5 at lines 17-25; Figure 1 (reproduced below).

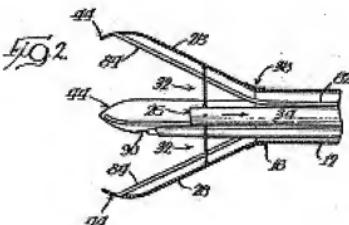


The retraction members 28 or levers can "matingly fit together to form a sheath having a pointed end for insertion through a surgical opening cut in a patient." Ash, page 6 at line 33 – page 7 at line 1; Figure 4 (reproduced below).



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The retraction members 28 can then be actuated to expand the distal end of the tube 12 to facilitate inspection with the viewing system. See Ash, page 5 at lines 27-31; Figure 2 (reproduced below).



Though the Examiner asserts that a person of ordinary skill in the art at the time of the invention could have “manufactured the elongated body of Foley with the expandable distal end of Ash” to provide the claimed system, there is no motivation to combine Foley and Ash in such a way.

As discussed above, Foley teaches conducting procedures spanning across areas significantly larger than the cross-sectional area of the cannula (e.g., a procedure extending from a pedicle of one vertebra and across a vertebral disc to a pedicle of an adjacent vertebra) by using several small cutaneous incisions along the spinal midline for either sequential insertion of a cannula 20 through the incisions, or insertion of several cannulae 20 through the incisions. Through the use of multiple "small" cutaneous incisions, Foley teaches the limited retraction of tissue. This teaching is consistent with the dimensions provided in Foley for the cannula (i.e., a maximum diameter d_2 of 12.7 mm). Therefore, Foley effectively teaches away from distal expansion of the cannula, because such expansion would result in increased retraction of tissue. Moreover, if multiple cannulae (modified to incorporate the expandable distal end of Ash) were inserted through the small cutaneous incisions in the Foley procedure, the cannulae would interfere with each other when their distal ends were expanded, particularly in procedures where the vertebrae (e.g., cervical vertebrae) are very close together. Further, the use of multiple small cutaneous incisions, which results in limited retraction of tissue, teaches away from the insertion of a single larger cannula through a larger incision for procedures spanning across areas significantly larger than the cross-sectional area of the cannula (e.g., a procedure extending from

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a pedicle on one vertebra to a pedicle on an adjacent vertebra), as this would result in increased tissue retraction.

Additionally, as discussed above, Foley does not teach simultaneous insertion of at least two fasteners and/or a vertebral fixation assembly through a single access device to fix two adjacent vertebrae. Further, Foley teaches successively dilating tissue with a series of tissue dilators of increasing diameter, and insertion of the cannula 20 over the largest dilator. See Foley, Col. 10 at lines 35-59; Figures 10b-10e. The dilators have successively larger diameters, ranging from 5 mm to 9 mm to 12.5 mm for the largest dilator. Such insertion of the cannula 20 over the series of dilators would not be possible if the cannula 20 were modified to have the distal end of the tube 12 in Ash. As discussed above, the distal end in Ash, in the closed position, provides a sheath with a pointed end. Such a pointed end of the sheath could not be inserted over dilators, as taught by Foley. Moreover, if the cannula in Foley were modified to incorporate the expandable distal end of Ash, which has a pointed end, the distal end would have to be expanded in order to insert the cannula over the dilators, as taught in Foley. Insertion of the cannula with the pointed distal end in an expanded position over the dilators would result in an increased retraction of tissue, which would frustrate the implied teaching of limited tissue retraction in Foley. Therefore, not only does Foley teach away from using a pointed sheath, as disclosed in Ash, but use of such a pointed sheath would frustrate the use of the cannula with the set of successively larger dilators, as disclosed in Foley, to limit retraction of tissue.

Accordingly, Applicant respectfully submits that there is no motivation to combine Foley and Ash, not only because Foley teaches away from use of a cannula with an expandable distal end, but also because such an expandable cannula would result in increased tissue retraction and frustrate the implied teaching in Foley of limited tissue retraction. Additionally, Foley teaches away from using a single cannula for procedures spanning across areas significantly larger than the cross-sectional area of the cannula, as this would require a larger cannula than the one disclosed in Foley and would result in increased tissue retraction, again frustrating the implied teaching in Foley of limited tissue retraction. Therefore, Applicant respectfully submits that a *prima facie* case of obviousness has not been established because there is no motivation to combine Foley and Ash.

Matthews

The Examiner asserts that the combination of Foley and Ash disclose the invention as claimed except for the fasteners being pedicle screws and the system further comprising a fixation element, and that Matthews teaches such screws and fixation element.

Matthews discloses vertebral fixation of adjacent vertebrae with bone screws 30, a fixation plate 40 mounted on the screw 30, and linking members 44 spanning across the midline between the corresponding bone screws 30. See Matthews, Col. 7 at lines 24-35; Figures 1 and 3 (reproduced below).

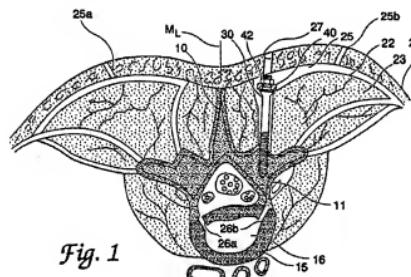


Fig. 1

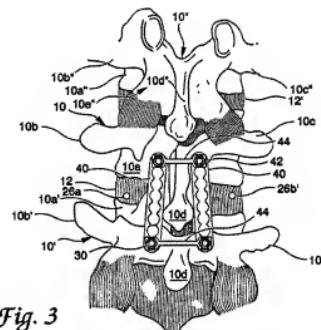


Fig. 3

Matthews also discloses that the bone screws can have a diameter of 5.5-8.5 mm. See Matthews at Col. 6, line 1. Additionally, Matthews discloses a set of dilators 50 for insertion of the bone screw into the vertebrae of a patient, wherein the largest dilator (through which the screw is delivered) has a cannulated diameter of 9.58 mm. See Matthews at Col. 8, lines 30-67; Figures 4A-4C (reproduced below).

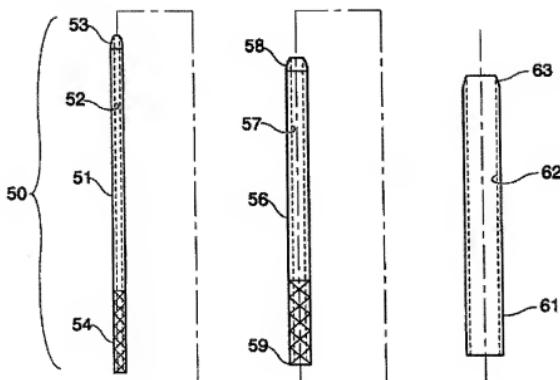


Fig. 4A

Fig. 4B

Fig. 4C

That is, even the largest of the dilators in Matthews is just large enough to accommodate delivery of a single bone screw. Accordingly, like Foley, Matthews teaches inserting a tube 61 for each screw to be placed, rather than inserting more than one fastener through a single access device. Column 6, lines 5-7.

Furthermore, although Matthews does teach use of a fixation plate 40, there is no teaching or suggestion in Matthews that the fixation plate 40 is delivered through the largest tube 61. Rather, Matthews describes using pick-ups and Metzenbaum scissors to dissect tissue in order to insert the fixation plate. Column 6, lines 8-15.

Thus, Matthews does not address shortcomings of Foley, discussed above, with respect to at least Claims 23-25, 27-30, 31-38, and 39-41. Additionally, Matthews, like Foley, fails to teach or suggest the particular structure of the elongate body, in combination with the other features, as recited by Claims 27 and 33 and their dependent claims.

Justis

With respect to Claims 25, 30 and 38, the Examiner asserts that the combination of Foley, Ash and Matthews disclose the claimed invention, except for the fixation element being a rod. See Office Action, page 3, ¶4. The Examiner asserts Justis discloses such a rod. Though Justis does disclose a stabilization system with an elongate member 22, which can be a spinal rod,

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Justis does not disclose such a stabilization system being delivered through an access device, as recited in the claimed embodiments, nor does Justis address the shortcomings of Foley, Ash and Matthews, as discussed above. Accordingly, Applicant respectfully submits that the Justis, in combination with Foley, Ash and Matthews fails to establish a *prima facie* case of obviousness at least with respect to Claims 25, 30 and 38.

Heinig

With respect to Claim 41, the Examiner asserts that the combination of Foley, Ash, Matthews and Justis disclose the claimed invention, except for the inclusion of a washer adapted to engage the convex engagement surface of the threaded fasteners. See Office Action, page 4, ¶5. The Examiner asserts Heinig discloses a surgically implantable device with such a washer. Though Heinig discloses a surgically implantable device 20 with a plate 22 positioned between a screw 49 and a nut 50 (see Heinig at Col. 4, lines 9-13; Figure 5), Heinig does not disclose that the implantable device is delivered through an access device, as recited in the claimed embodiments, nor does Heinig address the shortcomings of Foley, Ash, Matthews and Justis, as discussed above. Accordingly, Applicant respectfully submits that the Heinig, in combination with Foley, Ash, Matthews and Justis fails to establish a *prima facie* case of obviousness at least with respect to Claim 41.

Summary of Arguments

Applicant respectfully submits that while the five references cited by the Examiner teach devices suited for particular spinal operations, none of these references, alone or in combination, teaches or suggests the unique combination of features recited by each of Applicant's claims. As discussed above, Foley does not teach an access device configured for the simultaneous insertion of at least two fasteners and/or components of a vertebral fixation assembly through the same access device to fix two adjacent vertebrae. Additionally, there is no motivation to combine Ash and Foley because Foley teaches away from using an expandable distal end and because the combination of Foley and Ash would frustrate the teachings in Foley. Further, Matthews also only teaches a cannula that is just large enough to accommodate one fastener therethrough. Justis and Heinig also fail to address the shortcomings of Foley, Ash and Matthews.

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New Claims

New Claims 42-48 have been added to further claim the invention and distinguish the prior art. Applicant respectfully submits that these claims are allowable over the prior art relied upon by the Examiner for at least the same reasons discussed above. Therefore, Applicant requests the allowance of these new claims.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance in view of the above remarks. Any remarks in support of patentability of one claim, however, should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve such issues promptly.

For the foregoing reasons, Applicant respectfully submits that the present application is in condition for allowance, and Applicant respectfully requests that a Notice of Allowance be issued at the earliest opportunity.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

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Respectfully submitted,

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AMEND

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